K111538
OCT 25 2011 p1/2

Skeletal Kinetics

A COLSON ASSOCIATE

510(k) Summary

General Information as required by 21 CFR 807.92 (a) (1)

Submitters Name/address: Skeletal Kinetics® LLC
10201 Bubb Road
Cupertino, CA 95014, USA

Contact Person: Christine Kuo,
Director, Regulatory Affairs and Quality Assurance
Phone: (408) 350-5842, Fax: (408) 366-1077

Date Prepared: September 22, 2011

Device Name as required by 21 CFR 807.92 (a) (2)

Trade Names: CAAP (Calcium Apatite) Bone Wax

Common Name: Calcium phosphate bone wax

Classification: Unclassified

Product Code: MTJ

Predicate Devices as required by 21 CFR 807.92 (a) (3)

The subject device is substantially equivalent in safety and effectiveness to the following legally marketed devices (predicates):

I.	Auto Suture Bone Wax	K971680
II.	Ostene	K062280
III.	Ethicon Bone Wax	Preamendment
IV.	Lukens Bone Wax	K791495

Device Description as required by 21 CFR 807.92 (a) (4)

The single use CAAP (Calcium Apatite) Bone Wax sterile kit contains: Calcium Phosphate Powder, Dilute Sodium Silicate Liquid, and a Mixing System (Mixing Bowl, Pestle and Spatula). CAAP Bone Wax is to be mixed immediately prior to use.

Intended Use as required by 21 CFR 807.92 (a) (5)

CAAP Bone Wax is indicated to control the bleeding from cut or damaged bone by

acting as a mechanical barrier or tamponade.

Summary of Technological Characteristics as required by 21 CFR 807.92 (a) (6)

CAAP Bone Wax is composed of calcium phosphate and sodium silicate solution, when mixed together it forms a paste that can be applied directly to sites of bleeding bone, the resulting hardening material from the paste is composed of hydroxyapatite similar to the mineral phase of native bone tissue.

CAAP Bone Wax is substantially equivalent to previously cleared bone wax devices believed to control the bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade.

Predicate device I, K971680, Auto Suture Bone Wax (U.S. Surgical) is indicated in the control of bleeding from bone surfaces.

Predicate device II, K062280, Ostene (Ceremed) is indicated for use in the control of bleeding from bone surfaces.

Predicate device III, preamendment, Bone Wax (Ethicon Surgical) is to control bleeding from bone.

Predicate device IV, K791495, Lukens Bone Wax (Lukens) is acts as a mechanical barrier in achieving hemostasis in bleeding bone.

Summary of Non-clinical Tests as required by 21 CFR 807.92 (b) (1)

The biocompatibility of CAAP Bone Wax is in accordance with the standard set forth in ISO 10993-1, Biological Evaluation of Medical Devices and the radiation sterilization validation is in compliance to ANSI/AAMI/ISO 11137-2:2006, Sterilization of Health Care Products - Radiation - Establishing the Sterilization Dose.

The results of bench testing demonstrated that CAAP Bone Wax remains within the physiological pH and temperature range and would be expected to show no adverse biological consequence when applied as a physical hemostatic material.

The animal study provided substantial data that the use of CAAP Bone Wax as a mechanical tamponade **to control bleeding in a bony** site results in adequate hemostasis as compared with the predicate devices.

Summary of Clinical Tests as required by 21 CFR 807.92 (b) (2)

CAAP Bone Wax does not require clinical test.

Conclusion as required by 21 CFR 807.92 (3)

The summary demonstrates that CAAP Bone Wax is substantially equivalent to the predicate devices and is as safe, as effective and performs as well as the legally market devices identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 25 2011

Skeletal Kinetics LLC
% Ms. Christine Kuo
Director, Regulatory Affairs and
Quality Assurance
10201 Bubb Road
Cupertino, California 95014

Re: K111538
Trade/Device Name: CAAP (Calcium Apatite) Bone Wax
Regulatory Class: Unclassified
Product Code: MTJ
Dated: September 22, 2011
Received: September 23, 2011

Dear Ms. Kuo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

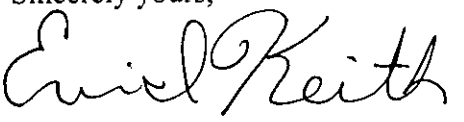
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: **Indications for Use**

510(K) Number (if Known): K111538

Device Name: CAAP (Calcium Apatite) Bone Wax

Indications for Use:

CAAP (Calcium Apatite) Bone Wax is indicated to control bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade.

Prescription Use (Per 21 CFR 801 Subpart D)	X	AND/OR	Over-the-Counter Use (21CFR 801 Subpart C	

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ed Keith

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111538